

REMARKS

I. Background

The present amendment and remarks are in response to the Office Action mailed January 5, 2010. Applicant has amended claims 13, 20-21, 24, and 34-35. As such, claims 13, 15-26 and 29-35 are currently pending for consideration on the merits.

Reconsideration of the claims is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited reference and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any reference discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Rejection on the Merits

A. 35 USC § 112 First Paragraph

The Office Action rejects claims 13, 15-26 and 29-33 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. Particularly, the Office Action objected to the terminology of "the first nutrient differentiation medium is not the second nutrient differentiation medium." Applicant respectfully asserts that the terminology is fully supported by the specification, which teaches that the cells are dispersed into another medium, i.e. fresh medium. In response to this rejection, Applicant has amended claims 13 and 24 to remove the language that was objected to and amended these claims to recite that the cells are dispersed into "a fresh second nutrient differentiation medium." This amendment has support in paragraphs [0020 and 0051-0052].

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under 35 USC § 112, first paragraph.

B. 35 USC § 112 Second Paragraph

The Office Action rejects claims 13, 15-26 and 29-33 under 35 USC § 112, second paragraph, as being indefinite for the same reasons recited in the rejection under 35 USC § 112, first paragraph, as recited above. The amendment to comply with 35 USC § 112, second first paragraph also complies with 35 USC § 112, second paragraph.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under 35 USC § 112, second paragraph.

C. 35 USC § 103

The Office Action rejects claims 13-15 and 17-19, 21, 23-34 under 35 USC § 103(a) as being obvious over *Cross et al.* (Biochemical Society Transactions 2001) in view of *Zhang* (In Vitro Cell. Dev Biol.-Animal (2001)). The Office Action also rejects claim 16 under 35 USC § 103(a) as being obvious over *Cross et al.* in view of *Zhang* as applied above and further in view of *Seijiro et al.* (US 4,654,304) and *Jefferson et al.* (US 5,380,660). Additionally, the Office Action rejects claims 20 and 22 under 35 USC § 103(a) as being obvious over *Cross et al.* in view of *Zhang* as applied above and further in view of *Judd et al.* (US 6,692,961) Applicant respectfully asserts that the Office Action has not established a *prima facie* case of obviousness because *Cross* is not a proper reference and is not valid prior art under a 103(a) rejection. Thus, all of the rejections recited in the Office Action are invalid.

Applicant submits herewith a Declaration of Jennifer Southgate, Ph.D. under 37 CFR 1.131 and 1.132, which provides evidence that the invention was conceived before the availability of the *Cross* reference. In fact, Jennifer Southgate, Ph.D. is a co-author of the *Cross* reference. Now, Jennifer Southgate, Ph.D. attests in the declaration that the experiments that were conducted to provide the characterization of stratified, terminally-differentiated human urothelium were performed prior to the publication of the *Cross* reference and prior to the availability of the *Cross* reference on December 18, 2001. Since the inventors conceived of the invention prior to December 18, 2001, the *Cross* reference is not available as prior art for this

patent application. Thus, the rejections relying on the *Cross* reference are defective and must be withdrawn.

Moreover, the Declaration of Jennifer Southgate, Ph.D. asserts that the inventive method claimed in the instant patent application provides the surprising and unexpected results of obtaining stratified, terminally-differentiated human urothelium. In fact, the stratified, terminally-differentiated human urothelium obtained from the claimed method was indeed characterized by experimentation to be stratified, terminally-differentiated human urothelium.

Furthermore, the claimed method indeed provides surprising and unexpected results because the Freshney reference (see Appendix B of the Declaration of Jennifer Southgate, Ph.D. filed herewith) teaches against the claimed method for producing stratified, terminally-differentiated human urothelium. Thus, obtaining stratified, terminally-differentiated human urothelium by the claimed method is indeed surprising and unexpected.

Since the *Cross* reference is not a valid reference under 35 U.S.C. § 103(a), and the invention as claimed was conceived prior to the public availability of *Cross*, the combination of *Cross* and *Zhang* and/or the combination of *Cross*, *Zhang*, *Seijiro*, and *Jefferson* and/or the combination of *Cross*, *Zhang*, and *Judd* is invalid and the rejections must be withdrawn. Moreover, the surprising and unexpected results obtained from the claimed method, which claimed method is contrary to the teachings of Freshney, effectively rebuts the obviousness rejections. Thus, a *prima facie* case of obviousness has not been established with respect to the currently pending claims. Thus, Applicant respectfully requests withdrawal of the rejection of claim under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made regarding the cited art or the pending application, including any Official Notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in any action at any appropriate time in the future, should

the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as the required motivation or suggestion to combine the relied upon Notice with the other art of record.

Applicant believes claims 13, 15-26 and 29-35 are in allowable form as discussed above. As such, Applicant respectfully requests reconsideration of the application and allowance of presently pending claims. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney by telephone at (801) 533-9800.

Dated this 17th day of June 2010.

Respectfully submitted,

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